

that has paid the enrollment fee on behalf of the discount card enrollee, during the calendar year during which the individual is determined eligible to receive transitional assistance.

(6) An endorsed sponsor may not charge an annual enrollment fee during the transition period.

**§ 403.812 HIPAA privacy, security, administrative data standards, and national identifiers.**

(a) *HIPAA covered entities.* An endorsed sponsor is a HIPAA covered entity and must comply with the standards, implementation specifications, and requirements in 45 CFR parts 160, 162, and 164 as set forth in this section. Those functions of an endorsed sponsor the performance of which are necessary or directly related to the operations of the endorsed discount card program are covered functions for purposes of applying to endorsed sponsors the standards, implementation specifications, and requirements in 45 CFR parts 160, 162, and 164.

(b) *HIPAA privacy requirements.* An endorsed sponsor must comply with the standards, implementation specifications, and requirements in the Standards for Privacy of Individually Identifiable Health Information, 45 CFR parts 160 and 164, subparts A and E, in the same manner as a health plan, except to the extent such requirements are temporarily waived by the Secretary.

(c) *Security requirements—(1) Standard.* An endorsed sponsor must comply with the applicable standards, implementation specifications, and requirements in the HIPAA Security Rule, 45 CFR parts 160 and 164, subparts A and C, in the same manner as other covered entities as of the compliance date of such Rule.

(2) *Attestation.* An applicant in its application shall—

(i) Attest that, as of the initial enrollment date, it will have in place appropriate administrative, technical, and physical safeguards to protect the privacy of protected health information in accordance with 45 CFR 164.530(c); and

(ii) Attest that its information security measures will meet the standards, implementation specifications, and re-

quirements of 45 CFR part 164 subparts A and C as of the initial enrollment date, or, if unable to make this attestation, provide a plan for coming into compliance with these requirements by the compliance date of the Security Rule set forth in 45 CFR part 164, subpart C.

(d) *Administrative data standards.* An endorsed sponsor must comply with any applicable standards, implementation specifications, and requirements in the Standards for Electronic Transactions under 45 CFR parts 160 and 162 subparts I through R.

(e) *Unique identifiers.* An endorsed sponsor must comply with any applicable standards, implementation specifications, and requirements regarding standard unique identifiers under 45 CFR parts 160 and 162 as of the compliance date of any final rule for standard unique identifiers.

(f) *Applicability of other regulations.* Nothing in this paragraph or in § 403.813 shall be deemed a modification of parts 160, 162 and 164 of title 45, Code of Federal Regulations or otherwise modify the applicability of such regulations to other organizations or covered entities independently subject to the mandates of HIPAA. If an endorsed sponsor is also a health plan, health care provider, or health care clearinghouse, nothing in this paragraph shall impair or otherwise affect the application of HIPAA or parts 160, 162 and 164 of title 45, Code of Federal Regulations to such entity and its performance of those functions which make such entity a health plan, health care provider, or health care clearinghouse.

**§ 403.813 Marketing limitations and record retention requirements.**

(a) *Marketing limitations.* (1) An endorsed sponsor may only market the following:

(i) Those products and services offered under the endorsed program that are inside the scope of endorsement defined in § 403.806(h) and permitted under § 403.812(b).

(ii) A Part D plan offered by the endorsed sponsor or an affiliated organization of the endorsed sponsor.

(2) An endorsed sponsor may not request that a drug card enrollee or an

individual seeking to enroll in its endorsed discount card program authorize the endorsed sponsor to use or disclose individually identifiable health information for purposes of marketing any product or service not allowed under paragraph (a)(1) of this section.

(3) An endorsed sponsor may not commingle any materials related to the marketing of products and services allowed under paragraph (a)(1) of this section with other marketing materials.

(4) Following termination of an endorsed sponsor's endorsement under §§ 403.820(c), (d) or (e) or termination of the Medicare Drug Discount Card and Transitional Assistance Program, a drug card enrollee's individually identifiable health information collected or maintained by an endorsed sponsor may not be used or disclosed for purposes of marketing any product or service.

(b) *Record retention standard.* (1) An endorsed sponsor must retain records that it creates, collects, or maintains while participating in the Medicare Drug Discount Card and Transitional Assistance Program as part of its operations of an endorsed program for at least 6 years following termination of such program, or, in the event the endorsed sponsor's endorsement is terminated under § 420.820(c), (d), or (e) of this chapter at least 6 years following termination of such endorsement. The Secretary may extend the six-year retention period if an endorsed sponsor's records relate to an ongoing investigation, litigation, or negotiation by the Secretary, the Department of Health and Human Services Office of Inspector General, the Department of Justice, or a State, or such documents otherwise relate to suspicions of fraud and abuse or violations of Federal or State law.

(2) For the period during which an endorsed sponsor retains records as specified in paragraph (b)(1) of this section, an endorsed sponsor must continue to apply security and privacy protections to such records and the information contained therein to the same extent endorsed sponsors are required to do so under §§ 403.812(b) and 403.812(c)(1) prior to termination.

[68 FR 69915, Dec. 15, 2003, as amended at 70 FR 52023, Sept. 1, 2005]

**§ 403.814 Special rules concerning Part C organizations and Medicare cost plans and their enrollees.**

(a) *General requirements.* (1) A Part C organization and Medicare cost plan may not require enrollment in an endorsed discount card program as a condition for enrollment in its Part C plan or Medicare cost plan.

(2) A Part C organization may subsidize the enrollment fee for an endorsed discount card program, whether operated by the Part C organization or another endorsed sponsor, for individuals described in § 403.810(a), provided that any such benefit is reflected in the Part C organization's Adjusted Community Rate filing.

(b) *Exclusive card sponsors.* (1) A Medicare managed care organization may elect to become an exclusive card sponsor by limiting enrollment in its endorsed discount card program to individuals described in § 403.810(a) who are enrolled in any of its Medicare managed care plans. The Medicare managed care organization must be the applicant for endorsement in order to offer an exclusive card program. Such an election must be made at the time of application for endorsement.

(2) Except as noted in paragraphs (b)(3) and (b)(4) of this section, an exclusive card sponsor must comply with all requirements for endorsed sponsors noted in §§ 403.804 and 403.806.

(3) An exclusive card sponsor is deemed to meet or is exempt from certain specific requirements listed in § 403.806 as follows:

(i) An exclusive card sponsor is deemed to meet the pharmacy network requirement in § 403.806(f)(3) if its pharmacy network is not limited to mail-order pharmacies and is equivalent to the pharmacy network used in its Medicare managed care plan and such pharmacy network has been approved by the Secretary, or, if its Medicare managed care plan does not use a pharmacy network, the Secretary determines that the pharmacy network provides sufficient access to covered discount card drugs at negotiated prices for discount card enrollees under the standard set forth under 42 CFR 422.112 for a Part C organization described in section 1851(a)(2)(A) of the Act, or